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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-------------|----------------------|---------------------|------------------|
| 10/037,477 | 01/02/2002 | Yoshihiro Takai | 18721-7053 | 5209 |
| 23639 | 7590 | 11/29/2004 | | EXAMINER |
| BINGHAM, MCCUTCHEN LLP | | | | CHURCH, CRAIG E |
| THREE EMBARCADERO, SUITE 1800 | | | | |
| SAN FRANCISCO, CA 94111-4067 | | | ART UNIT | PAPER NUMBER |
| | | | | 2882 |

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/037,477 | TAKAI ET AL. |
| | Examiner | Art Unit |
| | Craig E. Church | 2882 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10, 12-20, 22-30 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10, 12-20, 22-30, 34-39 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1 and 10 the steps

determining a relative position between at least one marker and

establishing a relationship of the at least one marker relative to the target

convey the same limitation and are redundant.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112 first paragraph as failing to support the invention as know claimed. There is no teaching in the original disclosure fo the the two steps

determining a relative position between at least one marker and

establishing a relationship of the at least one marker relative to the target

Claims 1 and 10 are rejected under 35 U.S.C. 112 first paragraph for the reasons set forth in the objection to the specification.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112 first paragraph as failing to provide an enabling disclosure. There is no teaching of how to acquire multiple images in a physiological cycle.

Claims 29, 30 and 37-39 are rejected under 35 U.S.C. 112 first paragraph for the reasons set forth in the objection to the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-7, 9, 10, 12-19, 22-30 and 34-39 are rejected under 35 U.S.C. 102(a) as being anticipated by Kunieda et al (6307914). Kunieda teaches a pursuing (tracking) radiation therapy system comprising a therapy x-ray beam generating LINAC 15, patient support couch 20 (called a base), first and second x-ray imaging systems 21a-f and 22a-f, markers 17 indicating tumor location, data processing means 24-32 for receiving data from the imaging systems and determining the dynamic location of the tumor and various controllers for adjusting the therapy apparatus in response to the detected tumor position. Lines 15-28 of column 9 explain such control includes gating source 15 on and off. Line 59 of column 15 to line 11 of column 16 teach that such control includes moving the patient couch (base). Lines 14-36 of column 16 mention that such control includes adjusting a multileaf collimator 15a. Lines 59-62 of column 11

reveal that the markers may be of various shapes and may be implanted in the patient. Lines 40-62 of column 16 suggest the use of multiple markers, and lines 36-51 of column 17 describe markers on the exterior surface of the patient which are imaged by TV cameras 1 and 2. Since Kunieda's imaging is of a human patient, it inherently occurs during a physiological cycle (the claims do not recite that the images are acquired during the *same* cycle). Columns 1 and 2 of Kunieda describe (prior art) tracking radiation therapy using the anatomy of a patient to locate a region to be treated and enabling radiation therapy.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunieda in view of Cosman (6459769). Kunieda does not suggest use of two beam collimators in series. Cosman discloses radiation therapy apparatus comprising first 12/16 and second 20/24 multileaf collimators, and it would have been obvious to equip the Kunieda device with a second MLC as taught by Cosman to enhance its ability to shape and control the therapy beam.

Applicant's arguments filed October 22, 2004 have been fully considered but they are not persuasive. What is the difference between the steps of

determining a relative position between at least one marker and establishing a relationship of the at least one marker relative to the target?

Applicant's assertions regarding claims 1 and 10 are in error. Lines 54 of column 7 to line 47 of column 8 of Kunieda explicitly explain how a relationship is established between a patient tumor 17 and marker 18.

Regarding claim 11 applicant has grossly misrepresented the Kunieda patent in stating that its multileaf collimator simply opens and closes. In fact lines 25-35 of column 16 explain

In the above embodiment 1, on/off control of the medical treatment beam 16 of the linac 15 is performed by obtained three-dimensional coordinates of the tumor marker 17. However, as shown in FIG. 20, if the moving body pursuit irradiating device is constructed such that the multi-leaf collimator 15a is opened and closed by the multi-leaf collimator control section 35 by performing an inverse operation from a moving amount of the tumor marker 17 and an irradiating field is dynamically controlled, the position of the tumor can be set to an irradiating object of the medical treatment beam at any time.

In other words, inverse opening and closing means that as the tumor moves across the treatment beam, one side of the collimator opens while the other side of the collimator closes so that the tumor remains centered in the beam.

Regarding claim 25, lines 66 of column 8 et seq explain how the tumor is tracked in three dimensions as the intersection of two straight lines which tracking signal influences enablement of the treatment beam, coordinated movement of the patient support, coordinated movement of the multileaf collimator etc.

Refarding claims 29, 30 and 37-39; since Kunieda's imaging is of a human patient, it inherently occurs during a physiological cycle (the claims do not recite

that the images are acquired during the *same* cycle). Lines 14-36 of column 16 mention that control includes adjusting a multileaf collimator 15a.

Regarding claims 34-36, columns 1 and 2 of Kunieda describe (prior art) tracking radiation therapy using the anatomy of a patient to locate a region to be treated and enabling radiation therapy.

Any inquiry concerning this communication should be directed to Craig E. Church at telephone number (571) 272-2488.



Craig E. Church
Senior Examiner
Art Unit 2882